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(71) Applicant(s)
Ian Francis Comaish
45 Kathleen Road, Battersea, LONDON, SW11 2JR, United Kingdom

(72) Inventor(s)
Ian Francis Comaish

(74) Agent and/or Address for Service
Fry Heath & Spence
The Old College, 53 High Street, HORLEY, Surrey, RH6 7BN, United Kingdom

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GB 2120947 A EP 0437248 A1 WO 91/07200 A1
US 4976704 A

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(54) Degradable surgical needle

(57) A surgical needle assembly comprises a needle 1 having a sharp end 3 which, in use, following insertion through body tissue, is arranged to degrade or soften over a period under the influence of physiological conditions, such that the sharp end 3 becomes blunt. The sharp end of the needle may be formed from hardened gelatins, poly-lactides, poly-glycolides, starches, or alginates such as sodium, potassium or calcium alginates. The needle may be a hypodermic syringe needle, cannula needle or catheter needle or may be part of an intravenous cannula assembly comprising a blunt inner tube 4 and an outer sleeve 2 having a bevelled sharp end 3 and formed from bioerodible or softenable material.

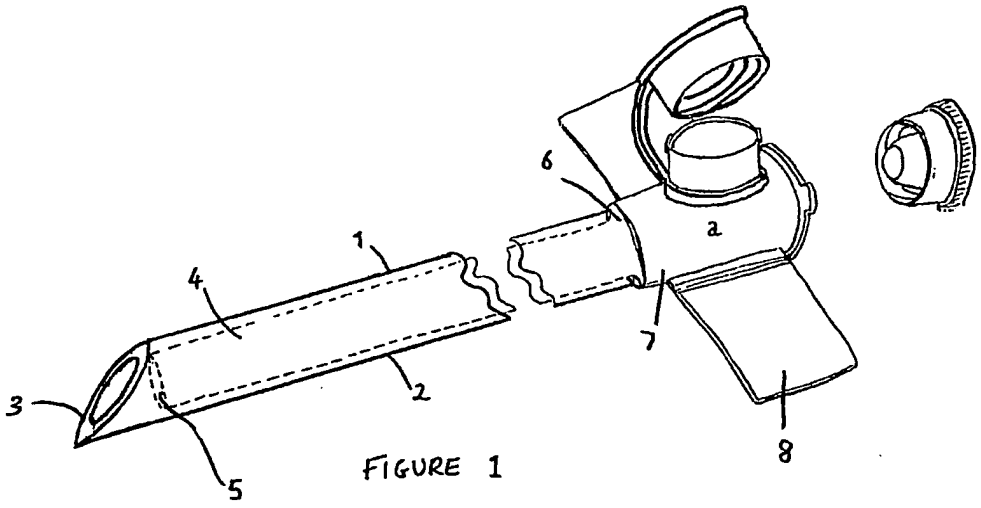

FIGURE 1

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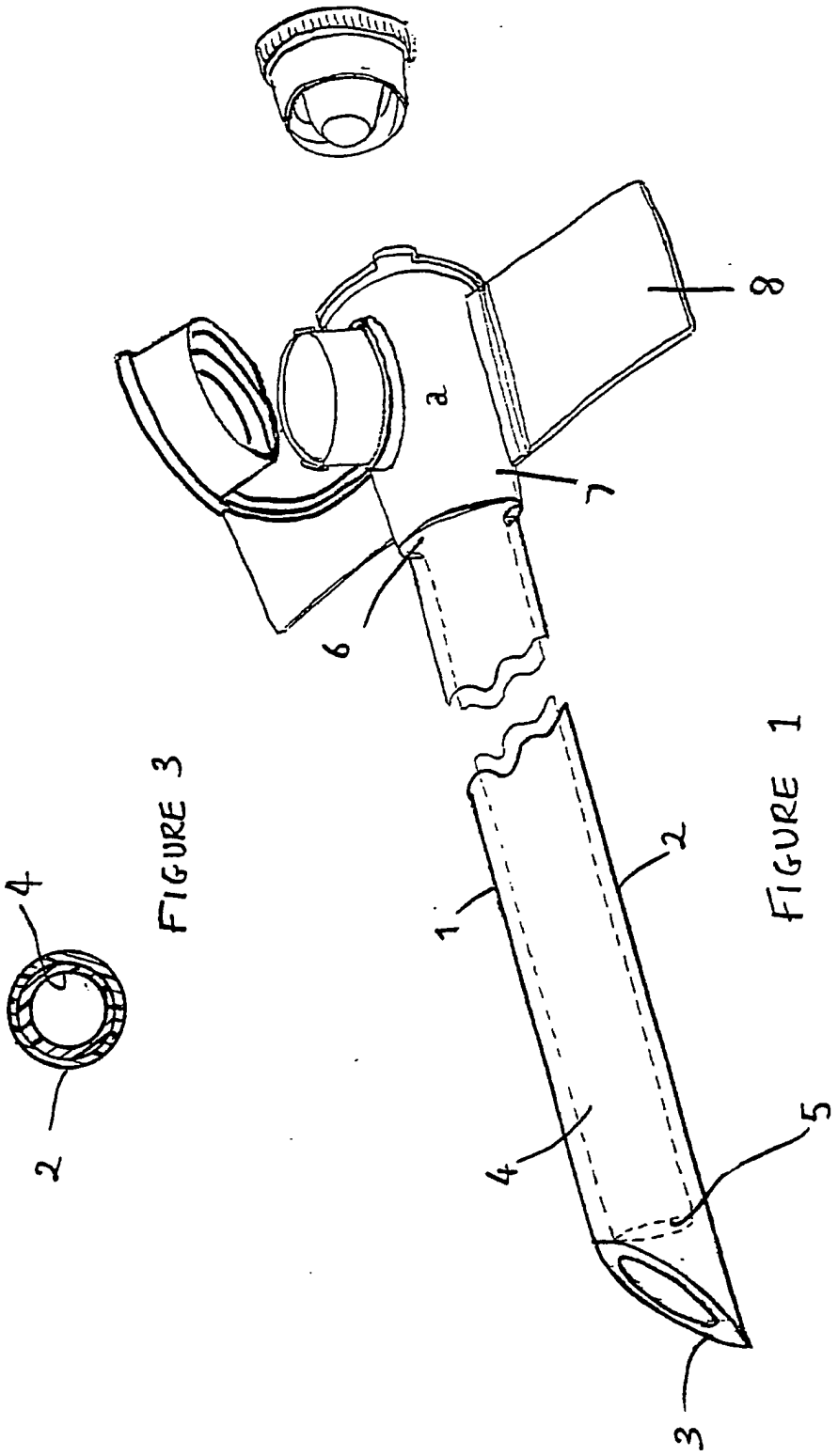

FIGURE 1

FIGURE 3

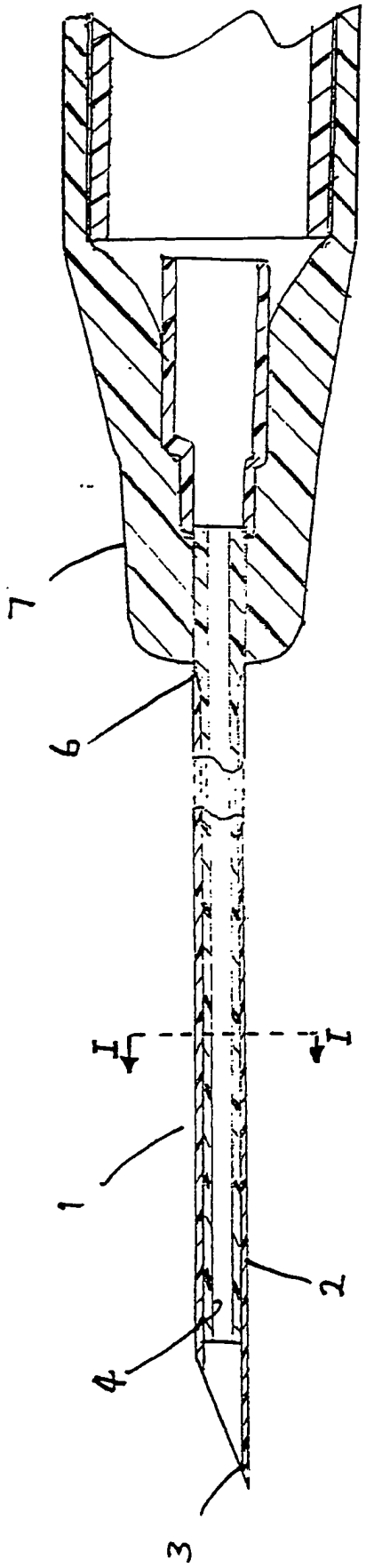

FIGURE 2

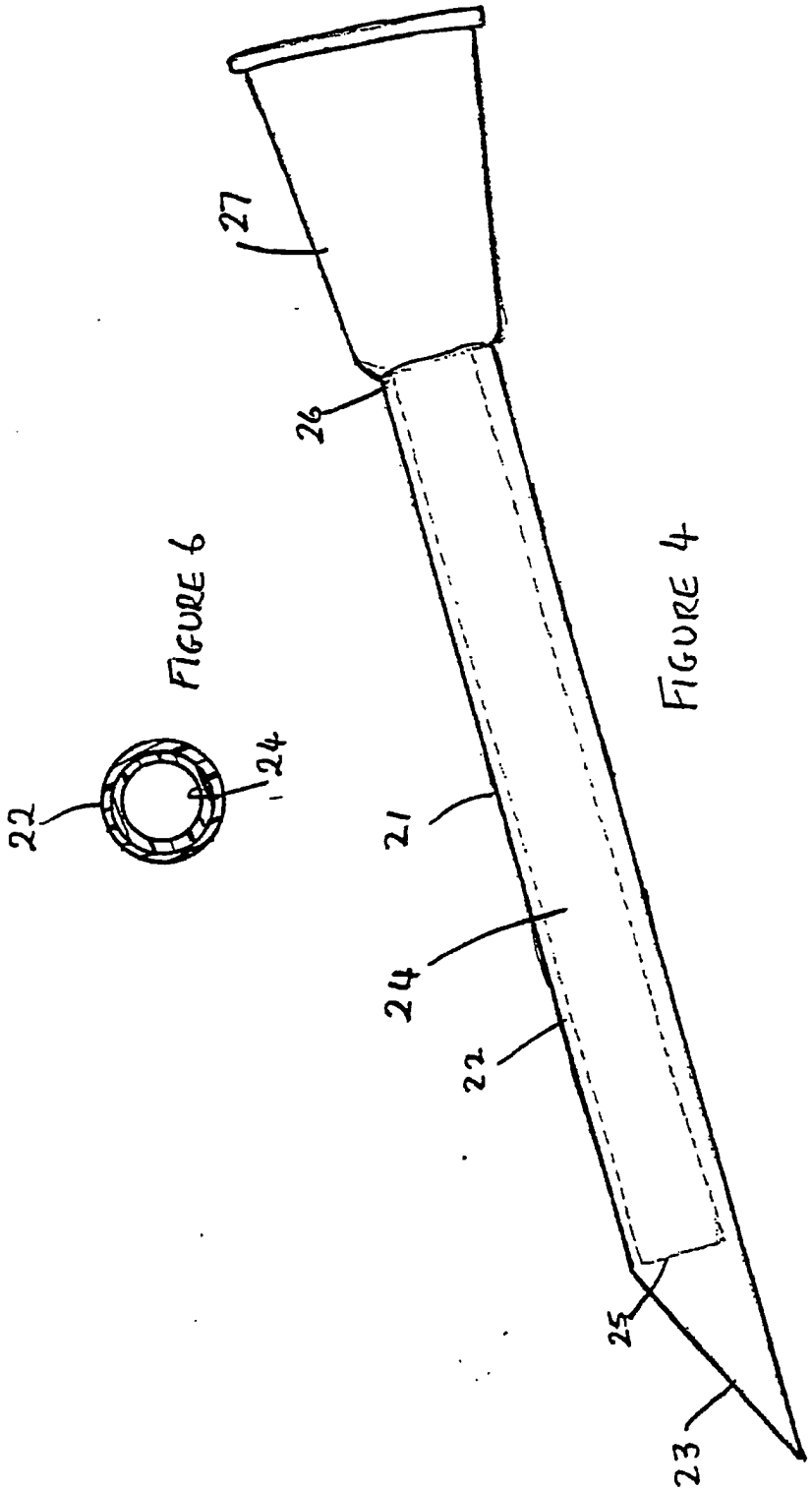

FIGURE 4

FIGURE 6

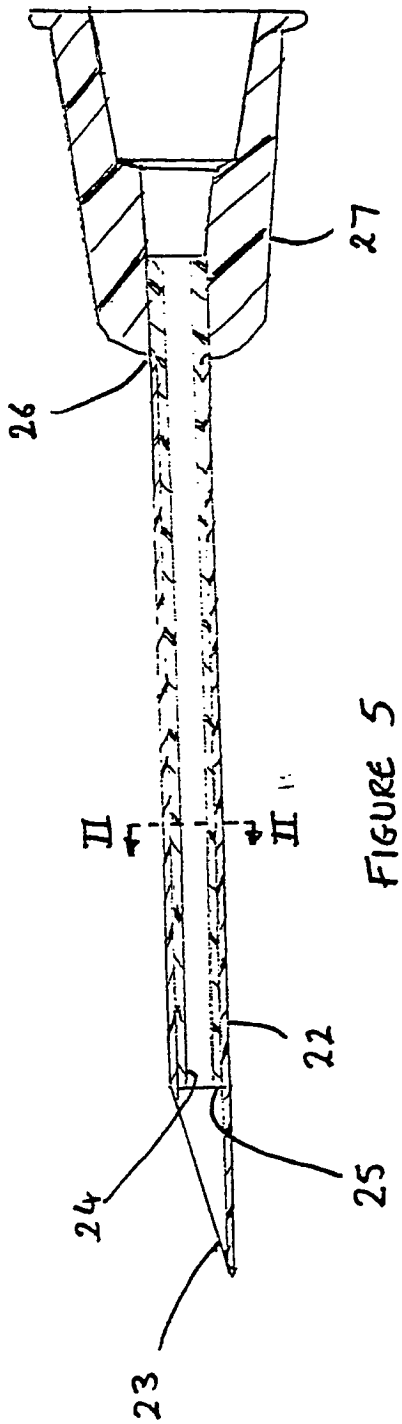

FIGURE 5

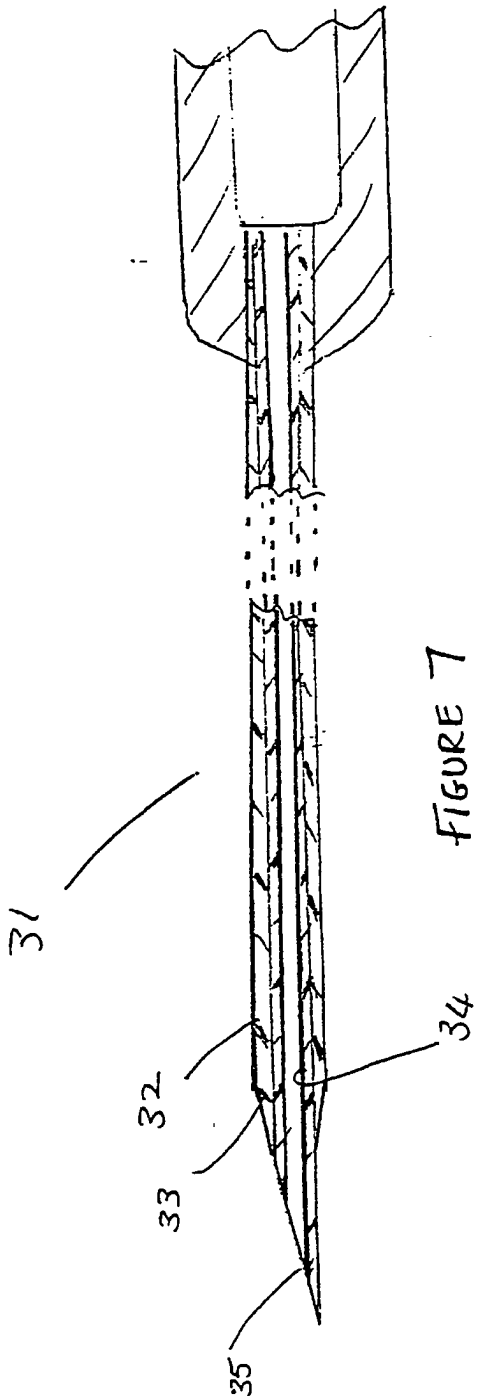

FIGURE 7

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SURGICAL NEEDLE ASSEMBLY

The present invention relates to a surgical needle assembly, such as a hypodermic syringe needle, cannula needle or catheter needle, e.g. a supra-pubic catheter needle.

A substantial problem associated with surgical needles is the problem of disposing of used needles. It is well recognised that used surgical sharps contaminated with blood or other biological fluids constitute a serious health hazard, and hence their disposal must be carried out in a careful and safe manner. This problem is common to hypodermic syringe needles and also to cannula and catheter needles.

A further problem concerns the design of certain intravenous cannulae currently in use. One common design of intravenous cannula comprises a blunt ended clear plastics tube for insertion into a vein, the tube having at one end thereof a luer lock connector enabling the

connection thereto of a drainage or supply tube, or to enable the connection thereto of a syringe. The blunt end of the plastics tube is itself incapable of piercing the wall of a vein, and thus a hollow metal introducer needle is provided which is slidably received within the bore of the plastics tube. The introducer needle has a sharp and bevelled pointed end and is of a length such that when fully inserted into the plastics tube, the point extends beyond the end of the plastics tube to enable it to reach the wall of a vein. The introducer needle is constructed so as to be removable from the plastics tube as soon as the whole cannula is sited, and is equipped with a finger grip and a viewing chamber which is in fluid communication with the needle point so that when the point breaches a vein, blood can flow freely into the viewing chamber indicating to the user that the vein has indeed been breached.

The introducer needle itself is only used to facilitate insertion of the plastics cannula tube into the vein and is thereafter removed and discarded. This gives rise to the health hazard and disposal problems described above. In addition, cannulae of this type suffer from the disadvantage that the viewing chamber on the introducer needle only indicates when the vein has been breached by the needle point, and does not inform the user whether the shorter plastics cannula tube has entered the vein. This can lead to mistakes in the insertion of the cannula tube and may necessitate the use of a further cannula unit, thereby incurring wastage. A still further problem with

such an arrangement is that the edge presented by the end of the plastics tube can snag against the wall of the vein and lead to difficulty in inserting the cannula tube.

The problems associated with the incorrect insertion of cannula needles, and the wastage which arises particularly in the hands of inexperienced staff, are well known.

It is an object of the present invention to provide a needle assembly which overcomes or alleviates to a significant extent the problems of incorrect needle insertion, and the health and disposal problems associated with contaminated needles and other surgical sharps.

Accordingly, in a first aspect, the invention provides a surgical needle assembly comprising a needle having a sharp end which, in use, following insertion through body tissue, is arranged to degrade or soften over a period under the influence of physiological conditions, such that the sharp end becomes blunt.

In one embodiment, the sharp end of the needle has at least an outer surface thereof formed of a polymer which erodes or softens under physiological conditions.

The surgical needle assembly can conveniently comprise a blunt-ended tube formed of substantially non-bioerodible material, the tube having extending from an end thereof a sharpened portion formed of a material which softens or erodes under physiological conditions.

The non-bioerodible blunt-ended tube may be formed as an inner sleeve having an overlaying outer sleeve which has

a sharp end and is formed from the bioerodible or softenable material. Alternatively, the blunt-ended non-bioerodible tube may have disposed within the bore thereof a sharp-ended needle-like member formed of the bioerodible or softenable material.

The bioerodible or softenable materials from which the sharpened end of the needle assembly is formed are typically biodegradable polymers which soften or degrade within a short period of having come into contact with body fluids such as blood. The biodegradable polymer should initially be rigid enough to present a sharpened end which maintains its integrity and sharpness long enough to penetrate the vein, but should thereafter begin to soften and/or break down under the physiological conditions (temperature 37°C and pH approx. 7.4) existing within the body tissues. Examples of polymers which can be used in accordance with the present invention include hardened gelatins, for example the hardened gelatins used in the manufacture of hard gelatine capsules; as well as poly-lactide and poly-glycolide polymers and copolymers thereof. Other bioerodible or softenable materials which may also be used include starches and alginates such as sodium, potassium, calcium alginates.

In a particular embodiment, the invention provides an intravenous cannula assembly having a cannula tube for insertion into a vein, the cannula tube comprising an inner tube which is blunt-ended and is formed of a substantially non-bioerodible material, and bonded to the outer surface

thereof an outer tube having a sharp end for breaching the vein, and being formed of a polymer which is erodible or softens under physiological conditions such that the sharp end becomes blunt.

The invention will now be illustrated by reference to the accompanying drawings in which:

Figure 1 is an isometric view of a cannula needle in accordance with one embodiment of the invention;

Figure 2 is a side sectional elevation of the cannula needle assembly of Figure 1;

Figure 3 is a sectional elevation along line I-I of the embodiment shown in Figure 2;

Figure 4 is an isometric view of a hypodermic syringe needle in accordance with the present invention;

Figure 5 is a side sectional elevation of the embodiment shown in Figure 4;

Figure 6 is a sectional elevation along line II-II in Figure 5; and

Figure 7 is a side sectional elevation along needle assembly in accordance with a further embodiment of the invention.

As shown in Figures 1 to 3, a cannula according to one embodiment of the invention has a needle assembly 1 comprising an outer sleeve 2 formed from a bioerodible or softenable material and having a bevelled sharp end 3. The bioerodible material may be, for example, a hardened gelatin, for example for the type used to prepare hard gelatin capsules. Disposed within the outer sleeve 2 is an

inner tubular member 4 formed a suitable medical grade non-bioerodible material such as polyethylene or PVC. As can be seen, the blunt end 5 of the inner tube 4 stops short of the end of the bore of the outer sleeve member 2.

The distal end 6 of the needle assembly 1 is secured within a hub member 7 in accordance with known bonding techniques. Hub member 7 comprises a luer lock arrangement of known type for the attachment thereto of drainage and supply lines or a hypodermic syringe. Wings 8, which are conventional in form, are provided to prevent rolling of the cannula assembly when inserted.

Figures 4 to 6 illustrate a hypodermic syringe needle in accordance with the present invention. Thus, the needle 21 comprises an outer sleeve 22 formed of a hardened gelatin or similar material, and having a sharp bevelled end 23. Disposed within and bonded to the inner surface of the outer sleeve member 22 is a non-bioerodible blunt-ended tube 24. The blunt end 25 of the inner tube 24 stops short of the opening at the end of the needle tip 33. The distal end 26 of the needle assembly is bonded to the needle hub 27 in conventional fashion.

An alternative embodiment of the invention is illustrated in Figure 7 wherein there is provided a needle assembly 31 comprising an outer tubular member 32 formed of a non-bioerodible material, for example hardened gelatin.

The end 33 of the plastics tube 32 is bevelled to assist insertion into a vein. Disposed within and bonded to the inner surface of the plastics tube 32 is an inner

tubular member 34 formed a bioerodible or softenable material such as a hardened gelatin. Inner tube 34 is provided with a sharp bevelled end 35 which extends beyond the end of outer tube 32. The distal end of the needle assembly 31 may be connected to the hub of a cannula, syringe needle hub, or a catheter hub, in accordance with known techniques.

In accordance with the invention, the needles may be inserted into the vein of a patient in the usual manner, the bioerodible polymer maintaining its integrity for sufficient time to allow the needle to be inserted into the vein. Following insertion, the needle end is relatively quickly degraded through hydrolysis under the physiological conditions, i.e. a temperature of approximately 37°C and a pH of approximately 7.4. Phagocytosis may have some effect also. As will be appreciated, when the cannula needle is finally removed from the patient, the result is a blunt-ended tube rather than a sharp, which of course is considerably less hazardous to dispose of than a conventional sharp needle.

A further advantage, particularly insofar as the embodiment shown in Figures 1 to 6 are concerned, is that there is no stepped edge to snag against the wall of a vein, during insertion, and consequently location of the needle in the vein is rendered much easier.

It will readily be apparent that numerous modifications and alterations may be made to the illustrated embodiments without departing from the

principles underlying the invention. For example, bioerodible polymers other than those specifically mentioned herein may be used provided that they maintain their integrity until the needle has been placed in position, and thereafter degrade or soften relatively quickly to give a blunt end. Such polymers may be arranged to degrade or soften at around normal physiological pH, but where the tissues or fluids with which the needle is intended to come into contact have a pH differing from approximately pH 7.4 the polymer may be chosen accordingly. For example, where the needle assembly forms a part of a supra-pubic catheter, in which the body fluids into which the catheter needle comes into contact are somewhat more acid, then the bioerodible polymer may be chosen such that it erodes or softens preferably under such pH conditions rather than at approximately 7.5.

All such alterations and modifications are intended to be embraced by this application.

CLAIMS

1. A surgical needle assembly comprising a needle having a sharp end which, in use, following insertion through the body tissue, is arranged to degrade or soften over a period under the influence of physiological conditions, such that the sharp end becomes blunt.

2. A surgical needle assembly according to Claim 1 wherein the sharp end of the needle has at least an outer surface thereof formed of a polymer which erodes or softens under physiological conditions.

3. A surgical needle assembly according to Claim 1 or Claim 2 comprising a blunt-end tube formed of substantially non-bioerodible material, the tube having extending from an end thereof a sharpened portion formed of a material which softens or erodes under physiological conditions.

4. A surgical needle assembly according to Claim 3 wherein in the non-bioerodible blunt-ended tube is formed as an inner sleeve having an overlaying outer sleeve which has a sharp end and is formed from the bioerodible or softenable material.

5. A surgical needle assembly according to Claim 3 wherein the blunt-ended non-bioerodible tube has

disposed within the bore thereof a sharp-ended needle-like member formed of the bioerodible or softenable material.

6. A surgical needle assembly according to any one of the preceding Claims which is a hypodermic syringe needle, a cannula needle or a catheter needle.

7. A surgical needle assembly according to Claim 6, in the form of an intravenous cannula assembly having a cannula tube for insertion into a vein, the cannula tube comprising an inner tube which is blunt-ended and is formed of a substantially non-bioerodible material, and bonded to the outer surface thereof an outer tube having a sharp end for breaching the vein, and formed of a polymer which is erodible or softens under physiological conditions such that the sharp end becomes blunt.

8. A surgical needle assembly according to any one of the preceding Claims wherein the sharpened end of the needle assembly is formed from hardened gelatins, poly-lactide and poly-glycolide polymers and copolymers thereof, starches or alginates such as sodium, potassium or calcium alginates.

9. A surgical needle assembly substantially as described herein with reference to accompanying Figures 1 to 7.

Patents Act 1977 Examiner's report to the Comptroller under Section 17 (The Search report)	Application number GB 9401518.7
Relevant Technical Fields (i) UK Cl (Ed.M) A5R (RCG, RGB, RGN) (ii) Int Cl (Ed.5) A61L 29/00, 31/00, A61M 5/158, 5/32, 25/06	Search Examiner L V THOMAS Date of completion of Search 25 MARCH 1994
Databases (see below) (i) UK Patent Office collections of GB, EP, WO and US patent specifications. (ii) ONLINE DATABASE : WPI	Documents considered relevant following a search in respect of Claims :- 1-9

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P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages		Relevant to claim(s)
X	GB 2120947 A	(NRDC) - see lines 25-29 and 52-66 page 1	1, 3, 6
X	EP 0437248 A1	(PFRIMMER KABI) - see lines 17-21 column 3	1, 3, 6, 8
X	WO 91/07200 A1	(BOSTON SCIENTIFIC) - see lines 22-31 page 2 and lines 9-14 page 3	1-3, 6
X	US 4976704	(McLEES) - see lines 46-61 column 1 and lines 34-38 and 50-62 column 2	1, 6

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